

**REMARKS**

This paper is responsive to the non-final Office Action mailed September 7, 2007. Claims 1 and 3-32 are pending in the application. Claims 1, 3-4, 6-9 and 12-31 have been rejected. Claims 5, 10, 11 and 32 were objected to as being dependent on a rejected base claim, but were indicated as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim.

**Rejections under 35 USC §102(b), or in the alternative §103(a).**

Claims 1, 3 and 22-29 stand rejected under 35 USC §102(b) as anticipated by, or in the alternative, under §103(a) as obvious over Lester (USP 5,928,198).

Claim 1, as amended herein, is directed to a tracheostomy tube comprising a hollow tubular body having a proximal end portion, a distal end portion and a curved portion intermediate said proximal and distal end portions. A flange situated at the proximal end portion is capable of selective attachment to the tubular body and removal therefrom.

The inventive tracheostomy tube is particularly advantageous when used in combination with a radially expandable introducer sheath, such as the sheath shown in Fig. 1 of the present application. When a radially expandable sheath of this type is utilized for the introduction of a tracheostomy tube that is fitted with a conventional flange that projects in the radial direction from the main body of the tracheostomy tube (visualize the radial projection of flange 15 from tube 1 of the device of Lester), the effective diameter of the tracheostomy tube resulting from the presence of the radial flange makes it difficult, if not impossible, to withdraw the radially expanded introducer sheath back over the tracheostomy tube following positioning of the tracheostomy tube in the trachea. In this instance, the flange portion of the tracheostomy tube would be situated directly in the path of the withdrawing sheath, thereby obstructing its withdrawal.

By utilizing a flange that may be selectively attached to, and removed from, the tubular body of the tracheostomy tube during a tracheostomy procedure, the tube can be introduced into the trachea via a radially expandable sheath, such as the sheath shown in Fig. 1. Following insertion, the removable flange is simply removed from the tubular body, thereby permitting the sheath to be withdrawn in the proximal direction. Use of a

radially expandable introducer sheath would not be possible with a tracheostomy tube such as that shown in Lester, having an integral radially expandable projection such as flange 15, because there would be no convenient way to remove the sheath following insertion of the tracheostomy tube.

Thus, as stated, the flange of the inventive device can be removed from the tracheostomy tube following insertion, and the introducer sheath can then simply be withdrawn in the proximal direction over the tube. As another alternative, the removable flange need not even be attached to the tracheostomy tube until the tube is in place in the trachea, and the introducer sheath has been withdrawn. Since the flange is not present on the tube when inserted, there is no radially extending structure present on the body of the tube to obstruct the withdrawal of the sheath. Following withdrawal of the introducer sheath over the tracheostomy tube, the flange can simply be attached, or reattached, to the tracheostomy tube, such as by a snap-fit.

As noted by the Examiner, Lester teaches a "movable" neck flange. There is nothing in Lester to suggest that this flange is capable of selective attachment to and removal from the tubular body, as claimed in amended claim 1. Rather, it appears that the flange is simply movable or slidable in some manner at the site of its attachment to the tube. The flange 15 of Lester is not capable of selective attachment to the tubular body and removal therefrom, as now claimed. Accordingly, Applicants respectfully submit that independent claim 1 is not anticipated by Lester.

As explained in the present application:

The tracheostomy tube can be conveniently inserted in proper position in the trachea using the combined tracheostomy tube/loading dilator of Fig. 6, and the radially expandable introducer sheath illustrated in Fig. 1. For insertion of the tracheostomy tube, the introducer sheath is initially introduced into a pre-dilated body opening. A dilator is then inserted as shown in Fig. 1 to provide a tracheal opening of designated size. The tracheostomy tube/loading dilator combination of Fig. 6 is then inserted through the tracheal opening. Once the tracheostomy tube is in proper position in the trachea, the introducer sheath is withdrawn.

When using a conventional tracheostomy tube having the flange attached thereto in conventional fashion, it would be difficult, if not impossible, to withdraw the introducer sheath from the body opening over the tracheostomy tube. The presence of the flange on a conventional tracheostomy tube acts to increase the effective diameter of the tracheostomy tube/dilator combination, thereby providing an obstruction to smooth withdrawal of the introducer. By utilizing a

tracheostomy tube for insertion that has not yet had the flange attached, or from which the flange has been removed, axially folded or otherwise manipulated in a manner such that it no longer obstructs removal of the sheath, the introducer sheath can be readily withdrawn in an axial direction over the tracheostomy tube. Once the sheath has been withdrawn, the flange can be simply snapped, extended, or otherwise affixed to the tracheostomy tube.

Application, Page 9, line 25 to page 10, line 14.

Thus, it is advantageous to be able to remove the flange, and thereby allow the introducer to be retracted proximally over the tracheostomy tube, and thereby attach (or re-attach) the flange so that it can be placed in abutment with the skin of the patient in well-known manner. Lester neither teaches nor suggests the structure as claimed herein. Nor does he provide any recognition of the problem involved, or any motivation why one skilled in the art would be led to utilize a flange that may be removed from the tracheostomy tube, as now claimed. Accordingly, claim 1 is also not obvious in view of Lester. Claims 3-11 depend, directly or indirectly, from independent claim 1, and include all of its limitations, including the limitation of a flange removable from the tracheostomy tube. Accordingly, these claims are also not anticipated by Lester, or obvious in view of Lester, for at least the same reasons specified above with regard to claim 1.

Claim 22, as amended, is directed to a device for percutaneous insertion into the trachea of a patient. The device includes a tracheostomy tube having a distal end portion percutaneously insertable into the trachea, and a proximal end portion exterior to the trachea when the distal end portion is inserted. The tracheostomy tube further has a radially extending flange capable of selective attachment to and removal from the tracheostomy tube after the distal end portion has been inserted into the trachea. A dilator is positionable within the longitudinal passageway of the tracheostomy tube for dilating an opening in the trachea. A locking assembly is provided for locking the tracheostomy tube to the dilator during insertion of said tracheostomy tube into the trachea.

As stated previously, Lester does not teach a radially extending flange capable of selective attachment to and removal from the tracheostomy tube after the distal end portion has been inserted into the trachea. Lester neither teaches nor suggests the

structure as claimed herein, nor does he provide any motivation why one skilled in the art would be led to utilize a removable flange, as now claimed.

Therefore, Applicants respectfully submit that claim 22 is not anticipated by, or obvious over, the Lester reference for at least the reasons referred to above with reference to claim 1. Claims 23-29 are dependent, directly or indirectly, on independent claim 22, and include all of the limitations of claim 22, including the limitation of the radially extending flange capable of selective attachment to and removal from the tracheostomy tube. Accordingly, these claims are not anticipated by, or obvious over, Lester for at least the same reasons specified above with regard to claim 22.

**Rejections under 35 USC 103(a).**

In the Office Action, Claims 12-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lester (USP 5,928,198) in view of Hazard (USP 5,058,580).

Applicants respectfully traverse this rejection. Lester discloses a tracheostomy tube having an obturator inserted through a bore in the tracheostomy tube. The obturator is molded from a "stiff but bendable, resilient plastics material", and includes a strap 20 of generally rectangular shape that forms the major part of the length of the obturator. The strap includes three semi-circular projections 21 that are positioned to hold the strap substantially centrally within the tracheostomy tube. (Col. 2, lines 40-50). The tracheostomy tube has a relatively blunt end that receives the bullet-shaped distal tip of the obturator. (Fig. 1). Hazard was cited for teaching a tapered distal end of a tracheostomy tube.

Claim 12 has been amended to specify that the smaller diameter distal portion of the dilator extends from the proximal portion, and has a generally cylindrical profile. This is shown, e.g., in Fig. 5 of the application. The obturator of the Lester reference comprises a generally flat or rectangular "strap" that extends between the proximal and distal portions. As a result, the smaller diameter distal portion does not extend from the proximal portion, but rather, extends from the flat strap portion. (See, e.g., reference numeral 20 in Fig. 2 of Lester). Neither of the cited references teaches, nor suggests, the arrangement as claimed herein. Therefore, Applicants respectfully submit that claim 12 is not obvious in view of the cited combination of Lester and Hazard. Claims 13-21

and 32 depend, directly or indirectly, from independent claim 12, and include all of its limitations, including the limitation wherein the smaller diameter distal portion of the dilator extends from the proximal portion. Accordingly, these claims are also not obvious in view of the cited combination for at least the same reasons that claim 12 is not obvious.

In addition to the foregoing, Applicants point out that the dependent claims are not obvious in view of the cited combination for at least the following additional reasons. With reference to claim 17 (as well as claims 18 and 19 dependent therefrom), the stepped portion 52 of the dilator 50 comprises a gripping surface. See, e.g., Fig. 6 of the application wherein stepped portion 52 is freely grippable during use. In the arrangement of Lester, the element 28 referred to by the Examiner as the grippable "stepped portion", is received within "collar" 12 of the tracheostomy tube. It is not positioned such that it can be gripped by a user during use. Thus, this internal portion is clearly not "grippable" within the meaning of the claims. Dependent claim 20 specifies that the dilator larger-diameter stepped proximal portion and smaller diameter distal portions comprise integral molded components. Dependent claim 21 specifies that the larger-diameter stepped proximal portion of the dilator includes a longitudinal passageway, and a portion of the smaller diameter distal portion is securely received within said longitudinal passageway. These arrangements are clearly neither taught nor suggested in the cited combination.

In the Office Action, claims 30 and 31 were rejected under 35 USC §103(a) as being unpatentable over Lester in view of Rutter (USP 7,140,369). Claim 30 is an independent claim directed to a method of inserting a tracheostomy tube into the trachea of a patient. The method, as amended, comprises the steps of: providing a tracheostomy tube comprising a hollow tubular body having a longitudinal passageway therethrough, said tubular body having a distal end portion for insertion into the trachea, and a proximal end portion exterior to the trachea when the distal end portion is inserted, said tubular body further having a curved portion intermediate said proximal and distal end portions; inserting said distal end portion of said tubular body into said trachea; trimming an excess portion of said proximal end portion of said tubular body;

and engaging a flange with said tracheostomy tube at said proximal end portion of said tubular body following insertion of the distal end portion of the tracheostomy tube.

The Examiner concedes that Lester lacks a detailed description of the claimed steps. Applicants have previously addressed the Examiner's points regarding engaging a flange with a proximal end of the tracheostomy tube body. In claim 30, as now amended, it is clear that the flange is engaged with the tracheostomy tube after the distal end portion of the tube has been inserted into the trachea. In the tracheostomy tube of Lester, the flange is not engaged with the tracheostomy tube after the distal end portion of the tube has been inserted into the trachea. This step is possible when utilizing a device as claimed herein, since the flange is selectively attachable to and removable from the tracheostomy tube. It is not possible with the device of Lester, without destroying or somehow reconstructing the device, since the flange is not otherwise removable from the tracheostomy tube.

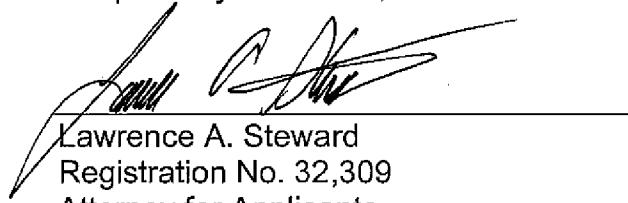
The present application provides a detailed explanation, reprinted in part herein in the quotation provided at pages 7-8, of how one may insert the tracheostomy tube of the present invention utilizing a radially expandable sheath as shown in Fig. 1.

According to the claimed method, once the tracheostomy tube has been inserted, a flange is engaged at the proximal end of the tubular body. This enables the physician to conveniently use the radially expandable introducer sheath as shown in Fig. 1, and thereafter simply withdraw the introducer sheath in a proximal direction over the tracheostomy tube prior to attachment of the flange. Nothing in the cited references discusses the problems that are overcome by the use of the removable flange as described, nor do they provide any suggestions why a skilled artisan would engage a flange at a proximal portion of a tracheostomy tube following insertion of the distal end portion of the tube. Therefore, Applicants respectfully submit that claim 30 is not obvious in view of the cited combination. Claim 31 is dependent on claim 30, and therefore, includes all of its limitations. Therefore, claim 31 is allowable for at least the same reasons that claim 30 is allowable.

**Conclusion.**

For the reasons provided hereinabove, Applicants respectfully submit that all claims 1 and 3-32 are in condition for allowance. Accordingly, Applicants respectfully request the prompt issuance of a Notice of Allowance. If the Examiner believes that prosecution may be advanced by a telephone conversation, the Examiner is respectfully requested to telephone the undersigned attorney.

Respectfully submitted,



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